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ONE HUNDRED NINTH CONGRESS

# Congress of the United States

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INDEPENDENT

September 15, 2005

Daniel R. Levinson  
Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Inspector General Levinson:

I am writing to ask that you investigate a matter involving the activities of Dr. James Battey, current Chairman of the National Institutes of Health Stem Cell Task Force. I believe Dr. Battey's activities may at least reveal systemic weaknesses that give rise to opportunities for waste, fraud and abuse, and therefore merit your attention.

On May 18, I wrote to Secretary Leavitt raising serious concerns about Dr. Battey's activities, specifically that:

- Dr. Battey "resigned" his post as the Chairman of the Stem Cell Task Force on March 18;
- After Dr. Battey's "resignation," he continued to give presentations related to his then-prior official duties;
- During this period, Dr. Battey was also widely reported to be a candidate for a high-profile position with the California Stem Cell Institute;
- Dr. Battey "resumed" his Chairmanship of the Stem Cell Task Force on May 6.

The timing and circumstances of Dr. Battey's activities raise serious ethical and conflict of interest issues. That Dr. Battey continued, after his "resignation," to make formal appearances on the matter of stem cell research as an employee of the NIH, while also publicly a candidate for the California Stem Cell Research Institute, appears to violate the NIH's own ethics guidelines, and implicates a systemic weakness allowing for fraud and abuse by senior employees at the National Institutes of Health.

I am enclosing the letter I sent to Secretary Leavitt on May 18, for which I have not received a response, outlining Dr. Battey's questionable activities. I ask that your office investigate this matter and report your findings to Congress.

Thank you for your consideration. Should you have any questions, please have a member of your staff contact the clerk of the subcommittee, Malia Holst, at (202) 225-2577.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark E. Souder". The signature is fluid and cursive, with the first name "Mark" being more prominent.

Mark E. Souder  
Chairman  
Subcommittee on Criminal Justice,  
Drug Policy, and Human Resources

Enclosure

CC: The Honorable Michael Leavitt, Secretary, Department of Health and  
Human Services

Dean Clancy, Associate Director for Human Resource Programs, Office of  
Management and Budget

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INDEPENDENT

May 18, 2005

The Honorable Michael Leavitt  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Mr. Secretary:

We are writing this letter to bring your attention to some matters of concern regarding Dr. James Battey, who allegedly resigned as Chairman of the NIH Stem Cell Task Force, but has since “un-resigned” (if that is the word) his Chairmanship of this important group.

On May 6, Subcommittee staff requested from NIH a list and transcripts of Dr. Battey’s speeches or public appearances since March 1 of this year, where the issue of stem cell research was a topic at those events. We received a response on May 9, listing **two** presentations (Smith College on March 4-5; Richmond, VA on March 18). We were told that “[t]hese were the only two presentations [Dr. Battey] made on Stem Cell Research during the time requested.”<sup>1</sup>

However, a brief search on the internet revealed at least one additional public appearance where the subject matter was stem cell research, so again on May 9 Subcommittee staff renewed the request for a list of “all public appearances since March 1 of this year” where Dr. Battey spoke on stem cell matters, and transcripts where available.

On May 11, we received a response listing **twelve** presentations.<sup>2</sup> It was in this response that we were also informed that Dr. Battey had “resumed” Chairmanship of the Stem Cell Task Force, a position from which he had resigned on March 18 citing the new NIH conflict of interest rules as prompting his resignation.<sup>3</sup> We were also told that transcripts were not available, except for Dr. Battey’s appearance on April 6, 2005 before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and related Agencies.

<sup>1</sup> Flambert, Gemma, email response to “Battey inquiry,” May 9, 2005.

<sup>2</sup> The chart provided to us listing these appearances is attached to this letter.

<sup>3</sup> The new conflict of interest rules were widely reported in the media, and the matter was a significant topic of your April 6 testimony before the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and related Agencies.

Important to this matter is the fact that Dr. Battey was a candidate for the position of President of the California Stem Cell Institute, which was widely reported and even referenced during his Senate testimony on April 6, 2005.

Between the period where Dr. Battey formally resigned his Chairmanship of the Stem Cell Task Force (March 18) and when he “resumed” Chairmanship (May 6)<sup>4</sup>, he made at least six public speeches or presentations on the subject of stem cell research, and numerous statements to the media on matters related to stem cell research.

The timing and circumstances of Dr. Battey’s actions in the last few months raises serious conflict of interest issues. Dr. Battey continued to make formal appearances on the matter of stem cell research as an employee of the NIH, while also publicly a candidate for the California Stem Cell Institute President. We have concerns that “resigning” the Chairmanship and later “un-resigning,” while making public speeches and statements related to the central issues of the Stem Cell Task Force appears improper, and perhaps violated the NIH’s own ethics guidelines.

First, it is unclear in what capacity Dr. Battey was making public statements and formal appearances dealing with stem cell research: Was it as a representative of NIH, and if so, as head of the Stem Cell Task Force? As the former head of the Stem Cell Task Force? As a job candidate for the California Stem Cell Institute? Obviously, the distinctions are important.

According to the ethics guidelines posted on NIH’s website, “an employee may engage in outside activities that require the use of professional qualifications readily identified with his or her NIH position, *provided his/her outside work does not create a real or an apparent conflict of interest* or interfere with regularly assigned official Government duties.”<sup>5</sup> The NIH also prohibits activities related to an employee’s official duties:

1. **Activities Must Not Be Related to Official Duties:** An employee may not receive compensation for outside activities that relate to his/her official duties and responsibilities as an NIH employee. An activity is considered related to current official work if:
  - it is done as part of official duties or the employee was invited to perform the activity primarily because of the employee’s official position, or
  - it deals with any matter to which an employee is presently assigned, or has been assigned during the previous one-year period; or
  - if it deals with any ongoing or announced policy, program or operation of the NIH.<sup>6</sup>

The NIH considers “giving formal speeches or presentations on a scientific or professional topic based on the employee’s personal expertise” as an outside activity.<sup>7</sup>

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<sup>4</sup> According to the material provided to us in the response to our request (Flamberg email on May 11, 2005).

<sup>5</sup> National Institutes of Health Ethics Program, Outside Activities, available at <http://ethics.od.nih.gov/topics/oa520.htm> (last visited May 16, 2005).

<sup>6</sup> Id.

<sup>7</sup> Id.

The Subcommittee is interested in whether Dr. Battey's public statements and appearances between the time he "resigned" and the time he "resumed" his chairmanship were "outside activities" for which he was compensated, and for which he must file a report, in accordance with NIH guidelines. If so, wouldn't such activities, clearly related to Dr. Battey's official duties during the last year, be prohibited by NIH ethics rules?

If Dr. Battey was not compensated, nevertheless the fact that he was speaking on these issues while also a candidate for the California Stem Cell Institute raises concerns. The NIH Ethics Program states that "a 'Conflict of Interest' arises when an employee is involved in a particular matter as part of his/her official duties with an outside organization with which he/she also has a financial interest, or one which is imputed to him/her, i.e.,... a person or organization with which the employee is negotiating for prospective or has an arrangement for prospective employment."<sup>8</sup>

What procedures were followed in approving Dr. Battey's high-profile appearances on a matter that is of such national significance, and for which he held a very prominent position?

Although we were informed that Dr. Battey is no longer a candidate for the California job, it is now unclear whether Dr. Battey has actually "rescinded" his resignation from NIH. In response to our last inquiry regarding Dr. Battey's employment status, we were informed that Dr. Battey "is hoping that the issues that he raised when he stated his intent to resign will be resolved so he can remain in his current position."<sup>9</sup>

Who in the department accepted Dr. Battey's resignation as Chairman of the Stem Cell Task Force? Who accepted Dr. Battey's "un-resignation," and restored him to the said chairmanship? To whom is the resignation reported? What effect does the resignation have on an employee's ethical obligations to the NIH and the Department?

Obviously, considering the importance and controversial nature of the stem cell issue, the appearance of integrity is paramount. However, this situation raises some troubling concerns that we hope you will address.

Finally Mr. Secretary, the last time we sent an oversight request to HHS dealing with critical stem cell research issues, we did not receive a response until after a very unreasonable delay, and the response was inadequate. Specifically, on October 8, 2002, Congressman Chris Smith and I requested "a detailed report" providing comprehensive information about the medical applications of adult and embryonic stem cells as well as stem cells from cloned embryos and aborted fetuses.

Our request was followed by numerous phone calls and a series of eight communications in writing over the subsequent 20 months. The response we finally received on June 18, 2004, stated that there were no treatments or ongoing clinical trials utilizing embryonic stem cells or stem cells from cloned embryos or aborted fetuses. The NIH letter also reported the adverse effects resulting from the two known clinical trials using fetal tissue transplantation to treat

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<sup>8</sup> National Institutes of Health Ethics Program, Conflicts of Interest, available at <http://ethics.od.nih.gov/Topics/coi.htm> (last visited May 16, 2005).

<sup>9</sup> Flambert, Gemma, email response to "House Government Reform Request," May 12, 2005

Parkinson's disease. This letter was signed by Dr. James Battey. However, the Subcommittee raised numerous material defects in the Department's response, particularly that the response did not address the plain meaning of the Subcommittee's original oversight request. (A copy of our letter to Secretary Thompson regarding this matter is attached.)

We ask that you address the issues raised in this letter regarding Mr. Battey's activities and his employment status, and look forward to receiving your response on these matters by May 27, 2005.

Thank you for your attention to this matter. If you have any questions, please have a member of your staff contact the clerk of the Subcommittee, Malia Holst, at (202) 225-2577.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Souder", with a stylized flourish at the end.

Mark E. Souder

Chairman

Subcommittee on Criminal Justice, Drug  
Policy, and Human Resources

Enclosure

Public Appearances and Speeches on Stem Cell Research  
Dr. James Battey

March 1	The Politics of Stem Cell Research: The Stem Cell Controversy	The National Institute of Science, Beta Kappa Chi Honor Society, The Omni Hotel, Richmond, VA
March 4-5	Stem Cell Conference	Smith College, Northampton, MA
March 9	Opening Address: "The Business of Stem Cell Research"	American Enterprise Institute, 1150 17 <sup>th</sup> Street, N.W., Washington, D.C.
March 15	Tribute Reception	Research!America, Tribute Reception, Willard Hotel, 1401 PA, Ave, N.W., Washington, D.C.
March 22	"Workshop on Stem Cell Research, Where is the Beef?"	Southern California of Biomedical Council, Los Angeles, CA.
April 6	Senate Appropriations Hearing	Senate Office Building, Washington, D.C.
April 11	NIH and Stem Cell Research	University of Utah, Genetic Science Learning Center, UT
April 18	Stem Cell Workshop	NIH, NIGMS, Pooks Hill Marriott, Bethesda, MD.
April 25	Business of Stem Cell Research Conference	Bethesda North Marriott Hotel and Conference Center
April 26	Georgetown Chapter of Sigma XI	Georgetown University, School of Medicine, Washington, DC
May 6	Research Dean's Meeting	AAMC, Ritz Carlton, Pentagon City, VA.
May 10	Presentation on Stem Cell Research	National Multiple Sclerosis Society, Mayflower Hotel, Washington, DC

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INDEPENDENT

July 9, 2004

The Honorable Tommy G. Thompson  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Secretary:

As Chairman Davis and I indicated in our letter dated June 17, 2004, over the past two years the Subcommittee on Criminal Justice, Drug Policy, and Human Resources and the office of Chairman Chris Smith have been in correspondence with the NIH regarding the current status of medical therapies and clinical research using adult and embryonic stem cells.

How the Department has allowed this matter to drag on for nearly two years defies excuse or explanation.

On October 8, 2002, Chairman Smith and I sent a letter to Dr. Elias Zerhouni, Director of the National Institutes of Health (NIH), requesting "a detailed report" providing comprehensive information about the medical applications of adult and embryonic stem cells as well as stem cells from cloned embryos and aborted fetuses.

After almost a year had passed, Subcommittee records indicate that on August 4, 2003, Subcommittee staff inquired into the status of the requested report and were told that the letter had been in the office of the Assistant Secretary for Legislation (ASL) "for some months" and would be out "in a few weeks."

On October 14, 2003, Subcommittee staff again inquired into the status of the report and were assured that although "...the letter is in final draft and is going through the clearance process now."



The written inquiries on the status of this report are recorded below. There were also numerous telephone conversations that are unrecorded here. The dates of correspondence from the Subcommittee to HHS regarding our October 8, 2002, letter are as follows:

August 4, 2003  
October 14, 2003  
October 27, 2003  
November 19, 2003  
February 10, 2004  
March 25, 2004  
April 20, 2004  
June 17, 2004

After repeated inquiries about the status of the report by email, I sent a formal, written letter to you, Mr. Secretary, on April 20, 2004.

Remarkably, there was no answer to the April 20 letter.

After waiting several weeks for acknowledgement, on June 17, 2004, Chairman Tom Davis of the House Government Reform Committee and I sent another letter communicating our concern about a number of outstanding correspondence and document requests.

On June 18, 2004, the Subcommittee received a letter signed by Dr. James Battey, Director of the National Institutes on Deafness and Other Communication Disorders (NIDCD) and Director of the Stem Cell Task Force, responding to our request for information regarding stem cell therapies.

However, the letter we received did not respond to the plain meaning of our request on October 8, 2002. Instead of a thorough response, it represented only a sampling of the information we requested. Through subsequent phone and email conversations within hours of receiving the response, Subcommittee staff communicated disappointment regarding the quality and depth of the letter we received and asked that the response be revised and completed by June 30, 2004.

In lieu of sending a revised document, at the close of the day on June 30, an HHS Deputy Assistant Secretary requested a meeting with members of the Subcommittee staff to "discuss the response on adult stem cells and how [NIH] may be able to better respond to your inquiries here."

At this meeting on July 2, Subcommittee staff communicated our frustration about the delay in receiving a response from the Department as well as our disappointment regarding the quality of the letter. In order to assist the Department in responding to the

Subcommittee's inquiry, I have included a summary of the meeting that took place, along with an outline of our agreement about the nature of a forthcoming, revised report in response to our October 8, 2002 written request.

The original letter, dated October 8, 2002 requested (*italics added*):

- “a *comprehensive* listing of *all* medical therapies” which utilize various types of stem cells,
- “a listing of *all* ongoing clinical trials or experiments involving human subjects using these same categories of stem cells,
- “the findings of *any* studies that utilized stem cells or tissues from embryos or fetuses to treat human patients from Parkinson's disease and juvenile diabetes,” and
- “a *listing of alternatives* to stem cells from embryos and fetuses that have shown promise in human subjects for treating juvenile diabetes, Alzheimer's, and Parkinson's disease.”

In response to our letter, the NIH stated that there are no treatments or ongoing clinical trials utilizing embryonic stem cells or stem cells from cloned embryos or aborted fetuses. The NIH letter also reported the adverse effects resulting from the two known clinical trials using fetal tissue transplantation to treat Parkinson's disease.

However, instead of a comprehensive listing of all medical therapies and a listing of all ongoing clinical trials in which human patients were being treated with adult stem cell therapies, NIH included a sampling of the work ongoing at some NIH Institutes and a listing of NIH-funded clinical trials.

That is not what was requested.

The Subcommittee identified several obvious omissions in Dr. Battey's letter.

- (1) From the NIH website [www.clinicaltrials.gov](http://www.clinicaltrials.gov), in the NIH National Library of Medicine *Medline* database, and in the popular press, Subcommittee staff identified extramurally funded clinical trials and clinical research involving human patients which were not included the NIH letter, including some that began as early as 1999 and should have been available to Dr. Battey prior to his submission of the letter to the ASL office in November 2002. A selection of extramurally funded clinical trials not included in the NIH letter are listed below:

- Sponsor: Baylor College of Medicine  
*Stem Cell Transplant to Treat Patients with Systemic Sclerosis*  
 Phase I H7157  
 Study start date: June 1999  
 Date last reviewed: March 2004
  
- Sponsor: Texas Heart Institute, Houston, Texas  
*Transendocardial, Autologous Bone Marrow Cell Transplantation for Severe, Chronic Ischemic Heart Failure*, announced in media April 16, 2004.  
[www.genomenewnetwork.org/articles/2004/04/16/stem\\_cell\\_trial.php](http://www.genomenewnetwork.org/articles/2004/04/16/stem_cell_trial.php)  
 Circulation. 2003 May 13;107(18):2294-302.
  
- Sponsor: Caritas St. Elizabeth's Medical Center of Boston  
*Stem Cell Study for Patients with Heart Disease* 00165  
 Study start date: January 2004  
 Date last reviewed: April 2004
  
- Sponsor: Bioheart, Inc.  
*Autologous Cultured Myoblasts (BioWhittaker) Transplanted via Myocardial Injection*  
 Phase I BMI-US-01-001  
 Study start date: June 2003  
 Date last reviewed: December 2003
  
- Sponsor: Bioheart, Inc.  
*MYOHEART™ (Myogenesis Heart Efficiency and Regeneration Trial)*  
 Phase I BMI-US-01-002  
 Study start date: February 2003  
 Date last reviewed: December 2003

In response, Dr. Battey maintained that the intent of NIH was to provide a comprehensive listing of work funded by NIH, but not by universities or pharmaceutical companies, citing the difficulty of enforcing compliance with a law (PL105-115, signed November, 1997) mandating that privately funded trials also be listed on the [www.clinicaltrials.gov](http://www.clinicaltrials.gov) website.

Nonetheless, Subcommittee staff were also able to identify several intramurally funded clinical trials at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), in which human patients are being treated with adult stem cell therapies, which, astonishingly, were not included in the NIH response:

• **NIAMS (National Institute of Arthritis and Musculoskeletal and Skin Diseases)**

*Autologous Stem Cell Transplant for Systemic Sclerosis*

Phase I N01 AR-9-2239

Study start date: July 2002

Date last reviewed: March 2004

• **NINDS (National Institute of Neurological Disorders and Stroke)**

*Investigating Endothelial Precursor Cells* 03-N-0269

Study start date: August 1, 2003

Date last reviewed: August 1, 2003

• **NHLBI (National Heart, Lung, and Blood Institute)**

*The Effect of Exercise on Stem Cell Mobilization and Heart Function in Patients Undergoing Cardiac Rehabilitation* 03-H-0086

Study start date: January 28, 2003

Date last reviewed: December 5, 2003

*Stem Cell Mobilization to Treat Chest Pain and Shortness of Breath in Patients with Coronary Artery Disease* 02-H-0264

Study start date: August 6, 2002

Date last reviewed: July 17, 2003

• **NIDCR (National Institute of Dental and Craniofacial Research)**

*Bone Regeneration Using Stromal Cells* 94-D-0188

Study start date: August 3, 1994

Date last reviewed: June 4, 2003

- (2) The Subcommittee also identified several reports of clinical research not yet in clinical trials that were also missing from the report. Some of these studies, reported in peer-reviewed journals and in the public media are listed below:

• **Preliminary clinical research using adult skeletal myoblasts to repair injured heart muscle:**

Pagani, et al, 2003. *Autologous skeletal myoblasts transplanted to ischemia-damaged myocardium in humans. Histological analysis of cell survival and differentiation.* J Am Coll Cardiol. Mar 5;41(5):879-88.

Hagege, et al, 2003. *Viability and differentiation of autologous skeletal myoblast grafts in ischaemic cardiomyopathy.* Lancet. Feb 8;361(9356):491-2.

Menasche, et al, 2003. *Autologous skeletal myoblast transplantation for severe postinfarction left ventricular dysfunction*. J Am Coll Cardiol. 2003 Apr 2;41(7):1078-83.

• **Autologous bone marrow or blood cells transplanted into injured heart:**

Dr. Cindy Grines at Beaumont Hospital, Royal Oak, Michigan:  
<http://www.cnn.com/2003/HEALTH/conditions/03/06/teen.heart.ap/>  
[http://www.sctline.com/info/english\\_viewarticle.asp?id=1966](http://www.sctline.com/info/english_viewarticle.asp?id=1966)

Assmus et, al, 2002. *Transplantation of Progenitor Cells and Regeneration Enhancement in Acute Myocardial Infarction (TOPCARE-AMI)*. Circulation. 2002 Dec 10;106(24):3009-17.

Dobert, et al, 2004. *Transplantation of progenitor cells after reperfused acute myocardial infarction: evaluation of perfusion and myocardial viability with FDG-PET and thallium SPECT*. Eur J Nucl Med Mol Imaging. 2004 Apr 3 [Epub ahead of print]

- (3) Included in the response from NIH was an enclosure from the National Bone Marrow Donor Program entitled "Diseases Treatable by Stem Cell Transplantation," dated 2002. However, this list contained only blood disorders, autoimmune diseases, and related cancers treatable with hematopoietic stem cells. The letter did not include a more updated, comprehensive listing of additional diseases treated with hematopoietic or other adult stem cell types.

When questioned about these omissions, Dr. Battey conceded that the report was not comprehensive. The wide range of information missing from the NIH response to our October 8, 2002 letter demonstrates the need for NIH to review responses to ensure that Congress receives accurate and thorough information in response to its requests.

Dr. Battey also indicated that he had made a decision when responding to the letter to include only NIH information that would be difficult for Congress to obtain through publicly accessible sources.

However, Subcommittee staff reiterated to HHS staff at the meeting that our request for a comprehensive document remained unchanged and unfulfilled.

In response to Subcommittee documentation of the inadequacy and omissions of the NIH response, Dr. Battey apologized.

Dr. Battey agreed he and his colleagues would assemble a comprehensive report as requested on October 8, 2002. Subcommittee staff agreed to give a time extension to the \$27 billion agency.

Dr. Battey and Subcommittee staff agreed that the revised report would:

- (1) be comprehensive in scope as originally requested, including both NIH funded research as well as privately funded research in the public domain, including studies abroad,
- (2) be in a format that is easily accessible and searchable,
- (3) include anecdotal reports of clinical research when these reports appear substantive and likely to lead to future clinical research and/or clinical trials, and
- (4) include only minimal analysis necessary for translating the factual components of the report into lay terms.

The Subcommittee staff and the Department also agreed that an iterative response would be provided to Senator Brownback in advance of his July 14, 2004, hearing on adult stem cell research.

Subcommittee staff emphasized that this report will be an invaluable resource as Congress seeks to make policy decisions and educate the public based on accurate and in-depth scientific data rather than the often-misleading information that is readily available from the news media and lobbying groups.

I appreciate your attention to this matter and your assurances that the Department will be more responsive to matters of Congressional oversight. This, as you know, is not a peripheral issue of concern only to a small number of people. I would think, on an issue of this magnitude, that HHS would have wanted to have this report available in response not only to Congress but for the President and others to whom such information might be important.

It is my hope that as members of Congress and their staff continue to face critical and complex science policy issues they will be able to draw on accurate, thorough, timely, and up-to-date information from the Department of Health and Human Services.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Souder", with a stylized flourish at the end.

Mark E. Souder,  
Chairman  
Subcommittee on Criminal Justice, Drug Policy,  
and Human Resources